REMARKS

The allowance of claims 21 and 22 is noted.

Claims 1-5, 13-20, 23, 28 40, 67-72, 75-77, 79-82 and 87-90 stand rejected under 35 USC 102(b) on the basis of Engelman.

Claims 1-7 stand rejected under 35 USC 102(b) on the basis of Mercer.

Claims 6, 11-12, 24-30, 33-36 and 38-39 stand rejected under 35 USC 103(a) on the basis of Engelman.

Claims 27 and 29 stand rejected under 35 USC 103(a) on the basis of Engelman.

Claims 31-32 stand rejected under 35 USC 103(a) on the basis of Engelman in view of Swartz.

Claims 73-74 stand rejected under 35 USC 103(a) on the basis of Engelman in view of Suzuki.

The rejection of any of the claims presently active in this application under 35 USC 102(b) on the basis of Engelman and/or Mercer is without basis and is not believed to be appropriate. The Examiner should recognize and appreciate that Applicants have gone to great length to draft claims that clearly define over Engleman and Mercer. It is therefore surprising that he Exmainer maintains the 102 rejection. The Examiner is also invited to review pages 41 to 48 of the Remarks submitted as part of the RCE containing an extensive discussion of Engelamn and Mercer and differentiating the claimed invention from these references. .

As discussed with the Examiner on several occasions, Engelman, true to the title of his patent, discloses a **leg elevator**. That is, Engelman shows a

board 11 with pad(s) intended to be located underneath a person's leg so as to raise the person's leg and ankle above a surface. There is **no** showing, teaching or suggestion in Engelman of having a pad shaped to enclose (a) the portion of the body part containing the bony prominence and (b) the bony prominence, as claimed in claim 1. Even the most cursory examination reveals that in Engelman there is **no** pad enclosing the heel and heel bone. There is also **no** showing, teaching or suggestion in Engelman of having a pad shaped to extend **continuously** between the area subtending the bony prominence and the support structure to increase the effective surface area over which the concentrated weight at the bony prominence is distributed. In Engelman the heel is elevated and disconnected from the underlying support surface. In accordance with applicants' invention the pad extends **continuously** between the area of the heel and the support surface to distribute the weight over a greater area. In sharp contrast, in Engelman a portion of the leg above the ankle is shown to rest on a pad to elevate the ankle. This transfers the weight to a different part of the body. It does not cause the weight at the bony prominence to be distributed over a wider area. Clearly, Engelman is directed to a different invention than the invention claimed in the instant application. Thus, though Engelman may be of general interest, Engelman does not show teach or suggest the claimed invention. Thus, Engelman does not anticipate the claimed invention under 35 USC 102 and/or USC 103.

With respect to the rejection based on Mercer directed to a **cast** , the Examiner must have overlooked the fact that claims 8, 9 and 10 were cancelled.

These cancelled claims were the only ones including language to a hard inner or outer shell.

Claim 2, dependent from claim 1, calls for the inner surface of the pad to be shaped to conform to the shape of the body part to be protected for enabling the body part containing the bony prominence to be positioned within the sculpted region and for increasing the surface area over which the weight of the body part and the bony prominence is distributed. There is no such showing or teaching in Engelman or Mercer.

Claim 3 calls for the pad material to be one of an elastic material, a compliant mushy foam, a generally compliant material and a mesh material; and wherein the bottom surface of the pad conforms generally to the surface of the support structure to increase the area over which the weight at the bony prominence is distributed as a function of the distance from the bony prominence to the support surface. This is not shown in Engelman and/or Mercer.

Claim 4 calls for pad material to be of the type which enables the inner, surface to conform to, and surround, the body part containing the bony prominence and also enables the bottom surface of the pad to conform generally to the surface of the support structure for enabling the pad to distribute the weight concentrated at the bony prominence over a larger area and **over an area which increases as the distance from the bony prominence to the support surface increases**. The "conic" distribution of the weight at the bony prominence over an increasing area as a function of the distance from the bony

prominence to the support surface is **not** shown taught or suggested in Engelman or Mercer.

Claim 5 calls for the thickness of the pad to be selectively increased to decrease the pressure at the interface between the bony prominence and the corresponding soft tissue layer; and wherein the body part to which the pad is applied can be freely moved in any direction. This is **not** possible with the structure of Engelman or the cast of Mercer.

Claim 6 recites some typical dimensions for the pad.

Claim 7 calls for the body part to be protected to be one of the heel, ankle, trochanter, knee, sacrum, coccyx, buttocks, ischium, scapula, elbow and occiput; and wherein the inner surface of the pad conforms to the shape of the body part containing the bony prominence of its respective body part and its outer surface is generally conformable to the support surface. This is not shown taught or suggested in Engelman and/or Mercer. Accordingly, the Examiner is requested to withdraw his objection to the allowance of this claim.

Claim 11 calls for the pad to be made of a soft material whose outer surface is generally conformable to varied support structures and having sufficient thickness of at least one quarter (1/4) of an inch to reduce the pressures developed within the body part to enable the body part to which the pad is applied to rest on the support structure for an extended period of time without developing a pressure ulcer between the bony prominence and the corresponding soft tissue layer of the body part.

Claim 12 dependent from claim 11 calls for the outer surface of the pad making contact with the support structure to conform generally to the shape of the support structure. This is not shown taught or suggested in Engelman (or Mercer). Accordingly, the Examiner is requested to withdraw his objection to the allowance of this claim.

Claim 13 dependent from claim 4 calls for the inner surface of the pad to conform to the shape of a heel and to extends from the arch to the ankle region and wherein the portion of the outer surface of the pad making contact with the support structure conforms generally to the shape of the support structure. This is not shown or suggested in the references. Accordingly, the Examiner is requested to withdraw his objection to the allowance of this claim.

Claim 14, dependent from claim 13, calls for the pad to be fitted so as to be worn by a user and to cover an area ranging from the arch to at least the ankle region of a user. None of the cited references show or suggested the claimed subject matter. Accordingly, the Examiner is requested to withdraw his objection to the allowance of this claim.

Claim 15, dependent from claim 1, calls for the body part to be protected to be the heel and for the pad to extend beneath the foot and the heel and to extends the full width of the foot and the heel and to be generally of cylindrical shape.

Claim 16, dependent from claim 1, calls for the pad to be shaped like a semi-cylindrical sleeve located behind the ankle and leg and extending from below the foot to above the ankle. None of the cited references show or

suggested the claimed subject matter. Accordingly, the Examiner is requested to withdraw his objection to the allowance of this claim.

Claim 17, dependent from claim 1, calls for the inner portion of the pad to extend around the bottom portion of the foot and ankle region and a portion of its shape being rectangular, cylindrical, semi-cylindrical, toroidal, ellipsoid, oblong, or triangular and/or a combination thereof. None of the cited references show or suggested the claimed subject matter. Accordingly, the Examiner is requested to withdraw his objection to the allowance of this claim.

Claim 18, dependent from claim 7, calls for each pad to includes means for securing the pad to its corresponding body part. .

Claim 19, dependent from claim 3, calls for each pad to be placed around its corresponding body part so as to protect the body part regardless of the orientation of the body part on, or off, the support structure.

Claim 20, dependent from claim 4, calls for the pad to be shaped to redistribute weight from the area of the bony prominence to other portions of the body part.

Claims 18-20 are submitted to be patentable for at least the same reasons as the claims from which they depend.

Claims 21 and 22 are allowed.

Claim 23 calls for a protective device to be applied to a body part having a bone structure which includes a bony prominence tending to concentrate the weight of the body part over a small region tending to increase the pressure at the interface between the bony prominence and its corresponding soft tissue

layer, and wherein the **protective device is shaped to reduce the pressure developed at the interface between the bony prominence and its corresponding soft tissue layer** for reducing the pressure that would cause a pressure ulcer to develop in that part of the body. Also, the protective device is shaped to increase the area over which the weight at the bony prominence is distributed as a function of the distance from the bony prominence to the support surface which may be a horizontal surface having a wide range of firmness.

Claim 24 calls for a protective device to be applied to a body part to be protected and placed between the body part containing the bony portion and a support surface; the protective device having an inner surface conforming to the body part to which it is applied and having an outer surface suitable for making contact with the support surface and generally conformable to the shape of the support surface for transferring the force due to the concentrated weight of the body part over a wider area; and the protective device having a thickness of a least one quarter of an inch and extending continuously from the region of the body part containing the bony portion to the support surface and the shape of the protective device being a function of the shape, size and weight of the body part and the bony portion for increasing the effective area and volume over which the concentrated weight present at the interface between the bony portion and its surrounding soft tissue layer is distributed and thereby reducing the pressure due to the bony point exerted at the interface between the bony portion and its corresponding soft tissue layer, across the corresponding soft tissue layer and at the interface between the corresponding soft tissue layer and the corresponding

outer skin and between the corresponding outer skin and the inner surface of the protective device whose outer surface is intended to be in contact with the support surface. Claim 24 is submitted to be patentable over Engelman for the reasons discussed for claims 1, 2 and 4 above.

Claim 25, dependent from claim 24, calls for the top surface of the pad to be sculpted to conform to the shape of the body part to be protected for enabling the body part containing the bony prominence to be positioned within the sculpted region and for increasing the surface area over which the weight of the body part and the bony prominence is distributed. This is not shown, taught or suggested in Engelman or the other references of record. Accordingly the allowance of claim 25 is respectfully requested.

Claim 26, dependent from claim 24, calls for the material between the top and bottom surfaces of the protective device to be of the type which enables the inner surface to conform to, and surround, the body part containing the bony prominence for causing the weight of the body part to be distributed over a greater area; and wherein the protective device is placed around the body part to protect the body part regardless of the orientation of the body part on the support surface. Claim 26 is submitted to be patentable for at lest the same reasons as claims 24, 1 and 5.

Claim 27, dependent form claim 24, calls for the protective device to be comprised of a generally rectangular cushion having a width of at least one quarter(1/4) of an inch and a length of at least one quarter (1/4) of an inch and the material between the top and bottom surfaces being one of an elastic

material, a mushy foam, a mesh material, and materials including, but not limited to, dressings, fibrous absorbents, fat-like substance such as silicon or wax, fleeces, foam, gauze, gels, hard shell conforming materials, hydrocolloids, moisture absorbing materials, moisture removing materials, permeable materials, materials which may change in thickness and stiffness, viscoelastic materials and a combination of the above. Claim 27 is submitted to be patentable for at least the same reasons as claim 24.

Claim 28, dependent from claim 24, calls for the protective device to be comprised of a generally semi-cylindrical sleeve.

Claim 29, dependent from claim 24, calls for the protective device to be comprised of a generally oblong cushion with a depression located opposite to the bony portion.

Claim 30, dependent from claim 24, calls for the protective device to include means for attaching the prosthesis to the body part.

Claims 28-30 are submitted to be patentable for at least the same reasons as claim 24.

Note: The Examiner had indicated that claim 31 would be allowable if rewritten in independent form. Applicants' attorney complied with that directive. However, it appears from the latest office action that the Examiner has not allowed claim 31 and has not given an explanation for his action.

In any event claim 31 has now been amended to emphasize that the inner surface of the protective pad **is sculpted**. Claim 31 calls for a protective device to be applied to a body part to be protected. Claim 31 has been amended to call

for the protective device to have an inner surface **sculpted to** conform to the body part to which it is applied and having an outer surface suitable for making contact with the support surface; and the protective device for distributing the weight of the body part and of the bony portion over an extended area and volume for effectively increasing the area and volume of the pressure cone and thereby reducing the pressure due to the bony point exerted at the interface between the bony portion and its corresponding soft tissue layer, across the corresponding soft tissue layer and at the interface between the corresponding soft tissue layer and the corresponding outer skin and between the corresponding outer skin and the inner surface of the protective device whose outer surface is intended to be in contact with the support surface; where the bony portion tends to concentrate the weight of the body part within a small region and wherein the protective device functions to increase the area and volume over which the weight is distributed; and **wherein there is included a layer of dressing between the outer skin layer and the inner surface of the protective device.**

Engelman in combination with Swartz does not show, teach or suggest, a protective device having an inner surface sculpted to conform to the body part to be protected and including a layer of dressing between the outer skin layer and the inner surface of the protective device. Accordingly, the allowance of claim is respectfully requested.

Claim 32, dependent from claim 24, calls for a layer between the outer skin layer and the outer surface of the pad like structure to allow the skin to breathe.

Claim 33, dependent from claim 24, calls for the body part to be protected to includes at least one of the heel, ankle, trochanter, knee, sacrum, coccyx, buttocks, ischium, scapula, elbow and occiput; and wherein the inner surface of the protective device conforms to its respective body part.

Claim 34, dependent from claim 24, calls for the thickness of the protective device to be selectively increased by adding layers to the outer surface of the protective device for further decreasing the pressure at the interface between the bony portion and its surrounding soft tissue layer.

The subject matter of claims 33 and 34 is not shown, taught or suggested in the references.

Claim 35 calls for a protective structure **enclosing the bony portion** of a body part to be protected and located between the bony portion of the body part to be protected and the support surface; said protective structure functioning as an extension of the soft tissue layer surrounding the bony portion and having **an inner surface sculpted to conforming to the body part** which it encloses and having an outer surface suitable for making contact with the support **surface and being generally conformable to the shape of the support surface for distributing the weight of the body part and the bony portion over a large area. The** protective structure having sufficient thickness and softness to distribute the weight of the body part over an extended area and volume such that the pressure exerted between the bony portion associated with the body part and its corresponding soft tissue layer, across the corresponding soft tissue layer and at the interface between the corresponding soft tissue layer and the

corresponding outer skin is less than the critical value of pressure (Pc) that would cause a pressure ulcer to develop in that part of the body; and wherein the protective structure is shaped to enclose the region of the body part containing the bony portion to increase the surface area at the interface between the bony portion and its surrounding soft tissue layer and across the soft tissue layer and between the soft tissue layer and the outer skin layer and between the outer skin layer and the support structure over which the concentrated weight is distributed for decreasing the pressure at the interface between the bony portion and the soft tissue layer surrounding the bony portion and within the soft tissue layer and at the interface between the soft tissue layer and outer skin below the critical value of Pc .

The elements claimed in claim 35 are not shown taught or suggested in Engelman. That is, Engelman does **not** suggest a structure (a) **enclosing the bony portion and (b)** having **an inner surface sculpted to conform to the body part, and (c) and being generally conformable to the shape of the support surface for distributing the weight of the body part and the bony portion over a large area; and being of sufficient thickness and softness to distribute the weight such that the pressure is less than the amount which would cause an ulcer. Accordingly, the allowance of claim 35 is respectfully requested.**

Claim 36, dependent from claim 35, recites that the critical pressure causing a pressure ulcer is a function of the length of time a given pressure is present, and calls for the protective structure to have selectable size, softness

and thickness, which may have different values as a function of the length of time the body part is to be on the support surface. The selection and setting the size, softness and thickness of a protective device as a function of the length of time the body part is on a support surface is **not** shown taught or suggested in the references. Accordingly, the allowance of claim 36 is respectfully requested.

Claim 38, **dependent from claim 35, recites that** the protective structure is **designed to change gradually** as a function of time to gradually increase the area and volume over which the concentrated weight is distributed in order to gradually reduce the pressure at the interface between the bony portion and the soft tissue layer surrounding the bony portion and within the soft tissue layer and at the interface between the soft tissue layer and outer skin of the body part to which it is applied. Having a protective structure which can change as a function of time is not suggested in the references.

Claim 39, **dependent from claim 35, recites that** selective characteristics of the protective structure including at least one of its thickness, softness, area, volume and compression modulus are selected so as to undergo change as a function of time for increasing the effective surface area and decreasing the pressure applied to the body part components. . Having a protective structure which can change as a function of time is not suggested in the references.

Claim 40 has been amended to emphasize that the inner surface of the protective pad includes a **cut out** to conform to the body part to be protected. Claim 40 calls for a protective pad applied between a body part to be protected

and a support surface. Claim 40, as amended, now calls for the pad having: (a) an inner surface which includes one of the following (i) **a cut out** to conform to the shape of the body part to be protected for enabling the body part containing the bony prominence to be positioned within the cut-out region; and (ii) a material and shape which enables the inner surface to conform to, and surround, the body part containing the bony prominence; and (b) having an outer surface suitable for making contact with the support surface and being generally conformable to the shape of the support surface for effectuating the transfer of the weight of the body part over a large area in order to reduce the pressure below a critical value which would tend to cause ulcers in the body part. A pad with an inner surface containing **a cut out to conform to the body part** is **not** suggested in Engelman.

Independent claim 67 and claims 68-76 dependent from claim 67 deal with the implanting of a pressure reducing device between the bony prominence and the adjacent soft tissue layer. No pertinent prior art has been cited. The examiner is invited to reread and review these claims to confirm that Engelman does not begin to address the claimed subject matter. For purpose of completeness we repeat the portion of the remarks submitted as part of the RCE.

Claim 67 calls for a bone to soft tissue interface pressure reducing structure **implanted** at the site of the bony prominence, which pressure reducing structure functions to increase the contact area between the bony prominence and the surrounding soft tissue and thereby causes the weight

due to the body part and the bony prominence to be distributed over a larger contact area with the soft tissue and to thereby decrease the pressure to which the soft tissue is exposed. The implanting of a bone to soft tissue interface pressure reducing structure shown, for example, in Figs. 22A-22D and Figs.21A-21D, is not shown, taught or suggested in any of the cited references. It is believed that the Examiner previously overlooked the significance of the **implant.** Accordingly, claim 67 is submitted to be patentable over the cited references. .

Claim 68, dependent from claim 67, calls for the bone to soft tissue interface pressure reducing structure to be **a pad inserted between the bony prominence and its surrounding soft tissue layer** and to be fabricated from a material of similar or greater firmness to that of the bony prominence and which behaves in a similar manner to the bony prominence.

Claim 69, dependent from claim 67, calls for the bone to soft tissue **interface pressure reducing structure to be fabricated from a material of similar or less firmness to that of the soft tissue** and which behaves in a similar manner to the soft tissue layer in diffusing the weight between the bony prominence and the actual soft tissue layer.

Claim 70, dependent from claim 67, calls for the bone to soft tissue interface pressure reducing structure to be a pad fabricated from a material having a firmness varying from that of the bony prominence to that of the soft tissue and to a firmness softer than that of soft tissue.

Claim 71, dependent from claim 67, recites that the bone to soft tissue interface pressure reducing structure is a pad fabricated from a material enabling the growth of at least one of new bone, new cartilage and new soft tissue in the region between the original bony prominence and the original soft tissue layer.

Claim 72, dependent from claim 70, recites that the pad material includes substances which serve as a matrix and seeding structure for the formation of new bone or new soft tissue or any suitable new matter.

Claim 73, dependent from claim 67, recites that the bone to soft tissue interface pressure reducing structure is a pad formed of a fatty like substance which exhibits little, if any, dimensional change as a function of time.

Claim 74, dependent from claim 73, recites that the fatty substance may be one of silicone and wax which exhibit little dimensional change as a function of time.

Claim 75, dependent from claim 67, recites that the bone to soft tissue interface pressure reducing structure is a pad formed of material having a first volume when first implanted and which expands to a predetermined size after implantation.

Claim 76, dependent from claim 67, recites that the bone to soft tissue interface pressure reducing structure is made of a material which dissolves over time.

It is submitted that claim 67 and claims 68 to 76 dependent directly or indirectly from claim 67 are clearly patentable over the references and their allowance is respectfully requested.

Claim 77 calls for **a hard shell-like structure** protective device **of limited size** to be applied to a body part requiring protection. The claimed structures are shown, for example, in Figs. 14A-14F for the heel, Figs. 15A-15C for the hip; Figs. 16A-16D for the ischium; Figs. 17A-17B for the coccyx; Figs. 18A-18B for the scapula; Fig. 19 for the occiput, and Fig. 20 for the elbow. This is not shown in the cited references and claim 77 is believe to be patentable over the references.

Claim 78 is cancelled without prejudice.

Claim 79, dependent from claim 77, names various of the body parts to be protected and that the inner surface of the shell-like structure conforms to its respective body part.

Claim 80, dependent from claim 79, recites that the inner surface of the shell-like structure includes a soft inner liner.

Claim 81, dependent from claim 79, recites that the outer surface of the shell like structure is covered with a soft material to prevent damaging or pressuring any other body parts.

Claim 82, dependent from claim 79, recites that the hard shell like structure is shaped to contour the body part to be protected and reduce pressure on the body part without immobilizing the body part.

Independent claim 77 and claims 79-82 are submitted to be patentable and to define patentably over the references.

Claim 87 calls for a **protective device for a bone structure which has undergone amputation, as** shown, for example, in Figs. 23A-23E and figs. 24A-24G. The protective device includes a pad applied to the body part to be protected having an inner surface conforming to the body part to which it is applied and having an outer surface suitable for making contact with the support surface and generally conformable to the shape of the support surface.

Claim 88 recites that the body part to be protected is one that has been amputated, and wherein the support structure is a prosthesis, and wherein the pad is placed between the amputated portion of the body part and the prosthesis. This is not shown or suggested in any of the references.

Claim 89, dependent from claim 88, recites that the pad is formed of a soft material.

Claim 90, dependent from claim 88, recites that the pad is formed of a hard material.

Accordingly, claims 87-90 directed to the protection of a limb which has undergone amputation are believed to be patentable over the cited references.

Respectfully submitted

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